

Notice of Allowability

Application No.

10/657,843

Examiner

Robert L. Nasser

Applicant(s)

MARK C. SHULTS ET AL

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to phone conversation of 4/22/2005.
2. ☒ The allowed claim(s) is/are 3,4,6-19 and 40-96.
3. ☒ The drawings filed on 09 September 2003 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date 2/2/2005
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

Art Unit: 3736

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Rose Thiessen on April 26, 2005.

The application has been amended as follows:

In the specification, in the paragraph inserted on page 1 , before line 2, the following has been added after the words January 21, 2000: -- Now US Patent 6,741,877 --.

In the claims:

In claim 6, line 5, the words -- adapted to be -- have been added before the word adjacent.

In Claim 6, line 10, the following has been added at the end of the claim: -- wherein one of the angiogenic layer and securing member is more proximal to the housing than other of the angiogenic layer and the securing member. --

In claim 17, line 6, the following has been added at the end of the claim: -- wherein one of the angiogenic layer and stability layer is more proximal to the sensor than other of the angiogenic layer and the stability layer. --

In Claim 45, line 8, the following has been added at the end of the claim: -- wherein one of the angiogenic layer and securing member is more proximal to the housing than other of the angiogenic layer and the securing member. --

Art Unit: 3736

In Claim 46, line 8, the following has been added at the end of the claim: -- wherein one of the stability layer and securing member is more proximal to the housing than other of the stability layer and the securing member. --

These amendments were made to define over, for example, the Updike et al article entitled Enzymatic Glucose sensors. Improved Long-term performance ... and the Gilligan et al article entitled Evaluation of a subcutaneous glucose sensor out to 3 months ... both references teach jacketing a glucose sensor in a Dacron housing for securing and for angiogenesis. The examiner notes that the references might be read to have a top layer that is angiogenic and a bottom layer that secures the device. However, both of these layers would be equally proximal or distal to the housing as the other. The claims were amended to define over such a reading by requiring one of the angiogenic layer or layer that induces formation of the foreign body capsule or the securing member or stability layer to be more proximal relative to the housing than the other layer or member.

The following is an examiner's statement of reasons for allowance: Claims 3, 4, 6-16, and 47-57 define over the art of record in that none of the art has an angiogenic layer and a securing member in combination with the sensor structure, as claimed. Claims 17-19 and 58-70 define over the art of record in that none of the art had an implantable analyte sensor with an angiogenic layer and a stability layer, as claimed. Claims 45 and 71-83 define over the art in that none of the art has the securing member and the angiogenic layer, as claimed. Claims 46 and 84-96 define over the art in that none of the art has the securing member and the stability layer that promotes formation of a foreign body capsule, as claimed.

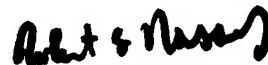
Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert L. Nasser whose telephone number is (571) 272-4731. The examiner can normally be reached on Mon-Fri, variable hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert L. Nasser
Primary Examiner
Art Unit 3736



RLN
April 26, 2005

ROBERT L. NASSER
PRIMARY EXAMINER